UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

DATE: April 16, 2002

SUBJECT: Inspection Report: IBA (formerly Griffith Microscience), Willowbrook, Illinois

FROM: Bonnie Bush, Environmental Engineer
Air Enforcement and Compliance Assurance Section (IL/IN)

THRU: Brent Marable, Chief
Air Enforcement and Compliance Assurance Section (IL/IN)

TO: File

Inspection Date: March 13, 2002

U.S. EPA Representatives: Bonnie Bush, Environmental Engineer
Bruce Varner, NESHAP Expert
Margaret Sieffert, Environmental Engineer
Manojkumar Patel, Environmental Engineer

Facility Representatives: Mark Bogs, Plant Manager
Stephen Dana Morris, Director, Environmental, Health and Safety

Company Description:
Plant Location: 7775 Quincy Street, Willowbrook, Illinois 60521
Phone Number: (630) 654-5151
Primary Contact: Stephen Dana Morris, (630) 928-1724

Purpose of Inspection and Background: Exemption 7(E)

Exemption 7(E)

IBA is a commercial ethylene oxide sterilizer of medical devices (95 percent), pharmaceuticals (1 percent), and spices and foods (3-4 percent). IBA, which stands for Ion Beam Applications, is a Belgian company that bought Griffith Microscience in May 1999, with U.S. headquarters located in Oak Brook, Illinois. The Willowbrook facility includes two sites, about a half block

apart. IBA/Griffith owns 10 commercial sterilizers in North America - 8 in the U.S., one in Toronto, Ontario, and one in Mexico. The Willowbrook sites run 20 percent of IBA's sterilization cycles in North America.

Entry Procedures: We arrived at IBA at 8:50 AM. We presented our credentials to the receptionist, who notified Mr. Bogs. Mr. Bogs escorted us to a conference room where we were joined by Mr. Morris.

Interview Information: Mr. Bogs presented an overview of operations at the Willowbrook sites. During his presentation, Al Taylor, Process Supervisor, joined us. The following information was provided by Mr. Bogs during his presentation. Griffith Microscience began sterilization at the Willowbrook Site 1 in 1984, with 8 sterilization chambers (1 3-pallet, 5 6-pallet, 2 13-pallet). In 1987, 3 more chambers were added (2 13-pallet, 1 6-pallet); in 1997-1998, 2 more were added (13-pallet); and in 2000, a research and development chamber (not subject to the NESHAP) was added. Site 2 began operations in 2000, with 3 sterilization chambers. Willowbrook sterilizes products from across the U.S. Some foods, including nuts, apricots, cocoa, and starches, are sterilized with propylene oxide, an unregulated sterilant. These foods are sterilized on a seasonal basis (winter holidays), only in Chamber 3 at Site 1. The Willowbrook facility runs 24 hours/day, 7 days/week, 52 weeks/year, and employs 35 at both sites. At both sites, there are 4 pre-conditioning rooms, 4 aeration rooms, and 11 aeration cells. The aeration cells are used infrequently for temperature sensitive products. Aeration cycles are 5 to 15 hours at Site 1.

IBA uses 100 percent ethylene oxide for sterilization and 100 percent nitrogen as a blanket (Freon was phased out before 1995). Some products are pressure-sensitive, requiring that less vacuum is pulled during sterilization; in this case, several nitrogen washes are employed at the start of the sterilization cycle. All the chambers are computer-controlled. Products are first held for 8 hours in a warehouse for temperature acclimatization. Products are then placed in a pre-conditioning room for 24 hours at a temperature of 110°F and 60 percent relative humidity. Site 1 has an ambient monitoring system for ethylene oxide, connected to a gas chromatograph (GC), with 16 sampling ports located throughout the facility. The work area is under negative pressure ventilation. The aeration rooms are under negative pressure; the operators wear respirators.

The Site 1 main sterilization chamber vents are exhausted to the Deoxx, an acid-water scrubber, which runs continuously. All evacuation phases of the sterilization chamber exhaust to the Deoxx. Flow rate through the scrubber is 80 gallons per minute (gpm). A new scrubber was added (the AAT) in 2000 with a dry bed reactor downstream, to meet the 2000 aeration room compliance deadline. The AAT flow rate is 1500 gpm. The original performance test of the AAT scrubber alone failed to meet the required reduction efficiency, so the dry bed reactors were added to the system. If the Deoxx goes down, the main chamber vent gases are routed to the AAT system, which performance tested at an overall 99.98 percent reduction efficiency in 1999. At Site 2, an AAT scrubber with dry bed reactor system controls both the main chamber vents and the aeration rooms. If the scrubber goes down, all gases can be routed to the reactor, which is designed for 99 percent reduction efficiency.

Site 2 began operations in 2000. While all 3 chambers operate, only 2 have been validated by customers. Validation is required by the FDA for only certain products. Site 2 was shut down once after an odor complaint, but the source of the odor was determined to be a chemical manufacturer in the area. Site 2 was then idled for a year due to market conditions, but started up again in March 2002. The pre-conditioning area operates at the same parameters as at Site 1. The aeration room cycle runs from 18 hours to 5 days, depending on the product.

Total ethylene oxide use is 40,000 to 45,000 pounds per month. The Willowbrook facilities have an agreement with the State Line Generating Station for back-up power generation. In 1998 a power surge took out the Deoxx, and now the facility has power surge protection on the controls. If there is a power loss, the ethylene oxide becomes locked in the sterilization chambers.

Facility Walk-through: We began the facility walk-through at 10:20 AM, accompanied by Mr. Bogs and Mr. Morris. We walked through the unprocessed storage area, where we observed one of the ambient GC sampling ports. The GC is calibrated at 1 part per million (ppm) ethylene oxide, with the low alarm set at 5 ppm to correlate with the OSHA short-term exposure limit of 5 ppm for 15 minutes. We then entered a pre-conditioning room and walked past the sterilization chambers. Nitrogen washes occur until the ethylene oxide level in the chamber is less than 0.75 percent, which is less than 25 percent of the lower explosive limit. Then the chamber door is opened, the back vent becomes operational for 15 minutes, and the pallets are then moved to the aeration chambers or cells. We entered the control room, where we met Roger Clark, the maintenance supervisor for the past 13.5 years, who informed us that there are 100 different sterilization cycles programmed for 70 customers.

Next we walked to the Deoxx unit. Gas from the chambers is pulled by vacuum pump to the Deoxx, where it flows up through a packed tower, countercurrent to the downward flow of water and sulfuric acid. After 25 minutes, the ethylene oxide has reacted to become ethylene glycol, which is pumped to a storage tank. IBA pays a broker who handles the ethylene glycol; some is sold for the manufacture of de-icer. IBA monitors the liquor level of the storage tank every week. The tank is drained about every 3 weeks. Liquor pH is checked once a week.

We then proceeded to the AAT system, which consists of an acid-water scrubber and 16 dry bed reactors, in a configuration of 8 units in each of 2 parallel beds. The bed material resembles sand. The system takes 15,000 cubic feet of gas per minute (cfm) from the aeration rooms. There is currently no routine monitoring of the reactors, other than quarterly readings taken with an organic vapor monitor at the system exhaust. The scrubber liquor level is monitored continuously, with a digital readout. The limit is 159 inches; at the time of inspection the level was 155 inches.

At 11:25 AM, we walked to Site 2. The sterilization process at Site 2 duplicates the process at Site 1, as does the control room set-up and safety systems. Therefore we observed only the emission control equipment at Site 2. There are 3 operating sterilization chambers currently at Site 2. There is space for future installation of an additional 2 chambers. There is no

ambient GC monitoring system at Site 2; levels are checked by a hand-held monitor.

The AAT scrubber at Site 2 is continuously monitored for liquor level, with a compliance parameter limit of 202 inches. The level at the time of inspection was 198 inches. The scrubber is of somewhat different design than the AAT scrubber at Site 1. The acid/water mix is pumped through the scrubber, top-to-bottom, at 1500 gpm. The scrubber tower is packed with plastic balls. Gas flows from bottom to top at 9000 cfm. Liquor from the bottom of the tower flows to a tank, which is adjacent and connected to a second tank at a height of 7 or 8 feet. The liquor spills over into the second tank at this level. The digital readout of the compliance parameter level is the level in this second tank. The compliance parameter level was determined by a March 2000 performance test. There are 10 dry bed reactor units downstream from the scrubber, 5 units in each of 2 parallel reactors. The air pollution control system is designed to handle 5 sterilization chambers. This concluded the walk-through.

Record Review and Closing Interview: We began the record review in the conference room at 1 PM. Records reviewed included annual Title 5 permit compliance certifications, compliance parameter monitoring records for 2000 and 2001 (scrubbers only), performance test results on the Deoxx and AAT systems, and semi-annual compliance reports. The OECA checklist was completed and is attached to this report.

I told Mr. Morris that U.S. EPA has serious concerns that the aeration room control system has run with no emission monitoring since the compliance deadline of December 2000. I told him that U.S. EPA had sent comments to IBA in October 2001 on IBA's proposal to use OSHA badges as a monitoring scheme, and that IBA had not yet responded to those comments. I asked Mr. Morris what IBA plans to do. Mr. Morris confirmed that OSHA badges had not been used during the March 2000 performance testing of the AAT systems. He stated that IBA plans to install GC continuous monitoring on the AAT systems. IBA will be able to use the existing ambient monitoring system at Site 1. A new GC system is on site at Site 2 but is not running yet. It was purchased as an ambient monitoring system, but Mr. Morris stated that he believes it can be used to monitor the aeration room exhaust levels. Mr. Morris at first estimated that it can be operational within 4 months. The AAT system at Site 1 had been in operation for 15 months at the time of inspection. The AAT system at Site 2 ran from January 2000 through March 15, 2001, and since March 1, 2002. Bed material has not ever been changed at either system. AAT advised IBA that the material would last for 18 months. During the closing interview, Mr. Morris took a call from Kathleen Morris, a vice president at IBA, who informed him that the GC system probably could not be operational for 6 months due to the installer's schedule. Mr. Morris stated that IBA plans to performance test at their Salt Lake City, Utah, facility within the next few weeks, and that they are trying to achieve 99 percent reduction efficiency using the scrubber alone. Mr. Morris said that he would send us a letter detailing their plans. (U.S. EPA received a letter from IBA on March 25, 2002.) I suggested to Mr. Morris that IBA should move as quickly as possible to install the GC continuous monitoring system. I also suggested that IBA should consider replacing the bed material as soon as possible, since its efficacy and efficiency is not known. This concluded the inspection, and we left the facility at about 3:30 PM.

Attachments

A. Inspection notes of Bonnie Bush
B. Inspection notes of Margaret Sieffert
C. OECA checklist
D. Plant layout of Willowbrook Site 1
E. Plant layout of Willowbrook Site 2